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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/416,267	10/12/99	SU	K PF270P1

022195
HUMAN GENOME SCIENCES INC
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HM12/0503

EXAMINER

MERTZ, P

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/416,267

Applicant(s)
Su et al.

Examiner
Prema Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 2, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-79 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. The amendment submitted in Paper No. 12, 3/2/01 has been entered. Claims 1-16, and 20-22 have been canceled previously. Claims 17-19, 23-24 have been canceled in Paper No. 12, 3/2/01. Claims 25-79 are pending and under consideration by the Examiner.
2. Receipt of applicant's arguments and amendments filed in Paper No. 12 (3/2/01) is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 10, 10/7/00:
 - (I) the rejection of claims 34-42 under 35 U.S.C. § 112, first paragraph, for compliance with deposit requirements.
4. Applicant's arguments filed in Paper No. 12 (3/2/01), have been fully considered but were persuasive-in-part. The issues remaining are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 U.S.C. § 101

6. Claims 25-79 are rejected under 35 U.S.C. 101.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action (Paper No. 10, 9/7/00).

Applicants argue that contrary to the Examiner's comments, Applicants have set forth in the specification statements that clearly and fully describe the function of Human Cytokine Polypeptide

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of the present invention. Applicants also argue that the specification, at page 3, lines 5-8, teaches that polypeptides of the present invention may stimulate cell proliferation and/or differentiation and on page 37, lines 7-13, teaches that polypeptides of the invention have uses, for example, in the detection of neoplasia. However, firstly, contrary to Applicants arguments, the particular cytokine claimed, has no utility till Applicants disclose what tissue or cell types the cytokine acts upon and the effects the cytokine has on the cells. For example if an antibody was claimed, it would not be disputed that the antibody was an antibody, but not knowing the antigen to which the antibody specifically binds, would make the claimed antibody not useful. Furthermore, the employment of the polypeptide of the instant invention, in the example cited by Applicants (in detection of neoplasia) is not a substantial or specific utility, because the cytokine protein has not shown to be associated with a disease or condition in any tissue. Furthermore, the protein has not been shown to be involved in regulation of the immune response.

Applicants assert that Graf et al (GenBank Accession No. CAC05581 (2000)) teach that the human twisted gastrulation homologue is identical in amino acid composition to the Human Cytokine Polypeptide of the present invention. However, Graf et al is a GenBank submission of a sequence submitted in the year 2000, after the filing date of the instant invention. Similarly, the Oelgeschlager et al reference which teaches that the twisted gastrulation gene encodes a secreted protein that is specifically required for the differentiation of amnioserosa cells in *Drosophila* and that it functions by direct interaction with BMPs, is irrelevant to the instant invention, since Applicants have failed to demonstrate that "the instant protein" has this biological function. In response to Applicants

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arguments that one of skill in the art, from this evidence would appreciate that the pending claims are supported by specific and substantial utilities, the Examiner asserts that, contrary to Applicants arguments, as set forth at pages 3-5 of the previous Office action (Paper No. 10, 9/7/00), the instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (*Sus. Ct.*, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the Court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. There has to be physiological significance for the Human Cytokine Polypeptide disclosed in the specification. It is inconceivable to use the claimed polypeptide, in the specific method described if one does not know what the cytokine does or what cells it acts on. Applicants have provided no evidence that the cytokine would stimulate cell proliferation and/or differentiation or would be differentially expressed in normal and neoplastic cells. The Brenner case has been cited for the position that a substantial, specific utility of a compound is required. There is no specific condition disclosed for which the protein can be used. This requirement is analogous to basic scientific characterization, however, in the instant case no substantial benefit for the cytokine is currently disclosed, but an exploratory significance. In the absence of a knowledge of the biological significance of the cytokine protein, there is no immediately obvious "patentable"

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use for it. To employ the protein of the instant invention in a method to stimulate cell proliferation and/or differentiation, is clearly to use it as the object of further research which has been determined by the Courts to be a non-patentable utility. Since the instant specification does not disclose a "real world" use for the protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

It is clear from the instant specification that the Human Cytokine polypeptide has been isolated because of its similarity to known proteins (page 14, lines 25-28). However, it is commonly known in the art that sequence-to-function methods of assigning protein function are prone to errors (Doerks et al. 1998). These errors can be due to sequence similarity of the query region to a region of the alleged similar protein that is not the active site, as well as homologs that did not have the same catalytic activity because active site residues of the characterized family were not conserved (Doerks et al., page 248, column 3, fourth and fifth paragraphs). Inaccurate use of sequence-to-function methods have led to significant function-annotation errors in the sequence databases (Doerks et al. Page 250, column 1, third paragraph). There is little doubt that after complete characterization, this protein will probably be found to have a patentable utility. The numerous uses of the claimed invention e.g. detection of neoplasia, stimulation of cell proliferation and/or differentiation, are not specific, substantial or credible utilities because Applicants have failed to disclose which condition or disease the instant polypeptide is associated with. Furthermore, since the instant protein has not been shown to be involved in the binding of a specific protein, has not been shown to be a disease marker, have enzymatic activity or to be involved in a physiological process that one would want to

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manipulate for clinical effect, such as regulate respiration, blood pressure, digestion, muscle relaxation, or neurotransmission, the instant specification does not disclose a "real world" use for the protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Furthermore, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be ascertained.

Claims 25-79 also remain rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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April 20, 2001